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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,833	06/23/2000	Alex Turner	8535-036-999	9468

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EXAMINER
LI, QIAN J

ART UNIT	PAPER NUMBER
1632	23

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/602,833	TURNER ET AL.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 June 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *10 March 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☒ The proposed amendment(s) will not be entered because:

(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *See Continuation Sheet*.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *1-6,8,21*.

Claim(s) withdrawn from consideration: _____.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

Continuation of 2. NOTE: Applicants question the propriety of the finality of Office action Paper:#19 based on the argument that the amendment narrowing the scope of the claims. Applicants argue "an increase of the size of the claimed fragment from 24 to 50 contiguou bases, should not have necessitated a further search". In response, the duty of the Examiner is applying appropriate prior art of record, not every possible prior art out there. The search strategies for a fragment of a nucleic acid molecule comprising different length of contiguous bases is different, thus, the search results may be overlap, but they are not co-extensive. This is evidenced by the fact that new art was revealed by the amended claims drawn to changed length of the contiguous bases for SEQ ID No: 1 or 3. In light of the number of sequences in today's sequence databases, it is impossible for the Office to search every possible art that covers sequence fragments having from 24-1116 contiguous bases . Therefore, it is proper to conduct new search for the amended claims, and it is also proper to make the action of Paper#19 final. Likewise, the purposed new amendment would require new search and consideration..

Continuation of 5. does NOT place the application in condition for allowance because: Claims 1, 3-6, and 21 stand rejected under 35 U.S.C. 102(a) as being anticipated by NCI-CGAP (EST database).

Since the amendments have not been entered, the rejection stands.

Applicants allege that the action is trying to cite the entire database. This is in error because the Office action (paper#19) clearly cited the accession number (AI399758) that anticipates the instantly claimed sequence in the EST database, which contain 64 contiguous bases o SEQ ID Nos: 1 or 3, respectively, and which share 100% best local similarity with the recited sequences, thus, hybridize with said sequences. The rejection is not based on the entire database nor possibilities.

Claims 1-6, 8, and 21 stand rejected under 35 U.S.C. § 101, AND under 35 U.S.C. 112, first paragraph, for lacking a specific and substantial asserted utility or a well-established utility, and for fails to provide an enabling disclosure to teach how to use the claimed invention.

In addition to providing similar arguments as in paper #16, applicants submitted additional evidence to support the arguments. However, the newly submitted evidence have not been considered because they are not directed solely to issues newly raised by the Examiner in the final rejection. The arguments drawn to new evidence are therefore moot.

With regards to whether the asserted utility is specific and substantial, Applicants in addition to providing similar arguments as in paper 16, further challenge the authorities of MPEP and new Utility Guidelines in the examination of patent applications, and argue it is the judiciary, not the USPTO, to interpret laws and rules. Applicants are reminded that the MPEP and new Utility Guidelines are set forth according to the many decisions of the judicial system. For example, Brenner v. Manson, 148 U.S.P.Q. 689 (1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that thi broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benef exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field . . . a patent is not a hunting license. . . .[i]t is not a reward for the search, but compensation for its successful conclusion".

With regard to whether based on the sequence homology, one could place the SGT4 in the family of LRR-containing protein family, and whether the specific utility of SGT4 could be supported by the utility of FLI-1 and RSU-1, applicants' representative attacking the credibilit of Bork reference on one hand, and taking certain sentences from Bork acknowledging the usefulness of the sequence homology analysi on the other hand. The arguments are not persuasive because the rejection is not based on Bork reference alone. The multiple reference cited by the Office from "old" to "new" are consistent in the power of sequence homology and function. Applicants are reminded that the intention of this Office is not to deny the power of sequence homology analysis, but based on the knowledge of homology studies to evaluate the utilities of the claimed sequence. A 30-50% similarity to the LRR domain of FLI-1 would not be considered as high in homology since even one amino acid change in a critical position could cause the change in peptide function, thus, the skilled artisan could not predictably place SGT4 in the family of Ras signal transduction proteins.

Applicants' representative also alleges that the cited references are "old", while ignoring the fact that references ranges from old to new, which illustrated that the general state of the art has not changed significantly over the years. Further, the court held: applicant's argumen based upon the age of the references, contentions that the reference patents are old are not impressive absent a showing that the art trie and failed to solve the same problem notwithstanding its presumed knowledge of the references. See In re Wright, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977). In fact, taking Everett et al (Nat Genetics 1997;17:411-22) as an example, the same group of authors use sophisticated computational modeling based on sequence homology to determine that the gene product causing Pendred syndrome was a sulphate transporter in 1997. However, subsequent research and investigation into the actual functional properties of the protein revealed that the protein was actually a chloride-iodide transporter and not a sulphate transporter as was originally predicted based on sequence homology (Scott et al, Nat Genetics 1999 Apr;21:440-443), this ratification was published in 1999. Therefore, the general knowledge and levels of skill in the art do not supplement the omitted description of the instant specification, because specific, not genera guidance is what is needed. Therefore, the 30-50% sequence homology alone is insufficient to place SGT4 in Ras signal transduction family, and/or to predictably foresee the function of SGT4 in the pathway. Thus, sequence homology alone is insufficient to provide a credible utility for SGT4.

For reasons of record and those set forth supra, the rejections stand..